Commentary

Promoting drug safety in elderly - Needs a proactive approach

Elderly population is increasing worldwide. In India, the size of the elderly population is fast growing, from 5.6 per cent in 1961 it is projected to rise to 12.4 per cent of the population by the year 2026¹. With an increasing share of population in this age group, it is natural to expect an increase in the problems associated with them as well. Health problems are supposed to be the major concern of this section of the society and it is estimated that one out of two elderly in India suffers from at least one chronic disease which requires lifelong medication². It is reported that use of medications has increased significantly among the elderly in the last decade³.

Even though the extent of research on drug related problems (DRPs) in elderly *per se* is limited in India, considering the population size and likely inherent problems in rational drug use in a developing country, the conducted studies revealed a high prevalence of irrational use of drugs among Indian elderly⁴⁻⁶. Polypharmacy is common among elderly patients⁵. These specific factors along with the inherent predisposing factors bring Indian elderly at risk for DRPs, mainly adverse drug reactions (ADRs).

In the prospective study conducted by Tiwari *et al*⁷. ADRs were found to be quite frequent in the geriatric clinic of a public teaching hospital at Chandigarh, India in a sample size of more than 4000 elderly outpatients. The figures reported are more of a real representation of the actual problem of ADRs among outpatients, this being an active monitoring study. On the other hand, in spontaneous reporting studies there is a higher probability of lack of identification and under-reporting of ADRs due to various reported factors. The data from this study will be useful addition to the limited available information from outpatient settings, as most of the ADR related studies are conducted among inpatients.

Prevalence of polypharmacy as depicted by the high average number of medications prescribed in the patients in the study, is a worldwide problem^{8,9} and Indian elderly could be even at a higher risk⁵. A share of 22 per cent of definitely preventable ADRs observed in the study is an indicator on the degree of preventability of drug use related problems among Indian elderly.

Advanced age: a significant predisposing factor for ADRs

Concerns on optimal use of drugs in the elderly are gaining momentum, in view of the ageing population and more medications reaching the market. It was reported that an estimated 99,628 emergency hospitalizations occurred due to adverse drug events in US adults 65 yr of age or older each year from 2007 through 2009¹⁰. In a recent Indian study conducted by Harugeri *et al*⁵, almost one third of the hospitalized patients were reported to have experienced an ADR.

Age per se does not result in an increased incidence of ADRs in elderly; it is indeed a result of multiple factors which occurs in this age group. Often, polypharmacy is the major reason contributing to DRPs which by itself is influenced by various factors. Multiple disease state exists in elderly patients, duplicative prescribing happens from multiple prescribers and in patients with inherent communication problems; misdiagnosis, unclear drug indications and use of drugs without indications can occur⁹. In a study conducted among geriatric patients in a teaching hospital in Ahmedabad, it was reported that 23.5 per cent of total patients received at least one inappropriate drug prescription⁴. There are age-related changes in physiology and body composition which influence drug handling, drug response and sensitivity in these patients¹¹. This in addition to poor compliance due to cognitive impairment and psychological status put these patients at a risk of ADRs³.

Use of traditional medicines is quite prevalent among Indians¹² which further increases the risk of drug-drug or drug-disease interactions and resultant ADRs. In the Indian health care setting, inadequate communication (an essential component compared to patients in other age groups) from health care providers on drug related aspects to patients or care givers can be a major contributing factor for ADRs. This could be true due to various factors; insufficient time spend by prescribers in explaining the treatment, inadequate education imparted by pharmacists on drug related aspects like proper dose regimen, major side effects; methods to prevent, identify, and action to be taken in case of ADRs and inadequate discharge medication counselling given by nursing staff.

Background literacy of many elderly patients keeps them at a disadvantage, when it comes to understanding the instructions given by health care providers. Elderly are at an additional risk of inappropriate drug use due to lapses from their care givers.

Improving safer use of medications in elderly

Methods to improve safe use of medications elderly should be a multidimensional and multidisciplinary approach. This should start from the point of patient visit and should be an ongoing process involving all steps of drug use, and frequently revisited for individual patients. Prescribing step needs to be refined and more cautiously approached while prescribing in geriatrics patients. Various tools for screening prescribing in elderly are available in practice which can assist prescribing which includes Beer's criteria¹³, STOPP (Screening Tool of Older Persons' potentially inappropriate Prescriptions)¹⁴. Though these criteria cannot replace the clinical judgment, such tools can help in reducing inappropriate prescribing in elderly and assist as quality assurance measures in reviewing drug use in any practice setting^{4,6}. Medications which are more frequently used in these patients as antidiabetics, oral anticoagulants and antiplatelets are the major culprits for ADRs¹⁰ as was observed in the present study also⁷. Safer use of these drugs can be promoted with appropriate education of patient, monitoring for adverse effects and frequent review for any drug interactions.

Appropriate history taking is a vital step and equally challenging due to various inherent difficulties in this age group. Ensuring the participation of patient's caregivers in this process is essential with evaluation of use of non-prescription medications and dietary supplements, allergy history, and experience

of any adverse effects or any other problem with the medications¹⁵. It is necessary to start with a low dose and titrate the medication dose slowly giving due consideration for the renal and hepatic function of the patient. Always use the least number of drugs, routinely review possible drug toxicity, and review concomitant medications and diseases to evaluate possible interaction with new drugs. Always weigh the risks and benefits of adding new drugs to patient's existing drug therapy¹⁶.

Good communication is crucial to ensure safe use of medications. Prescribers should develop an effective therapeutic partnership with the patient. Patient and caregivers should be well educated about the appropriate dose regimen; necessary details on side effects of the medications prescribed including methods for prevention, identification, managing and action to be taken in case of developing the same. Pharmacists need to be encouraged to take up a more active role in this process of patient education in collaboration with the prescribers.

Measures have to be taken to ensure frequent patient follow ups. Reassessing the need of drugs in the present dose regimen has to be given priority during the routine follow ups. Any drug related problem has to be assessed at every patient visits⁸. It should be considered that ADRs are often difficult to detect in older patients, because of their atypical or non specific nature among elderly, like lethargy, confusion, lightheadedness, or falls⁹. Patient adherence with the suggested regimen has to be reinstated at each visit. Studies have shown that 21 per cent of preventable ADRs in elderly outpatients were due to errors in patient adherence¹⁷.

Targeting high risk older adults has to be implemented as it is not practically possible to have an extensive approach for all the patients visiting the practitioners. Factors to be considered for targeting include medication related factors like polypharmacy and use of high risk drugs like anticoagulants, anticonvulsants, *etc.* Patient related factors include multiple co-morbidities, multiple prescribers, advanced age, dementia, regular use of alcohol, decreased renal function, those with history of ADR and history of recent hospitalisation⁸.

Geriatric pharmacotherapy need to be included as a crucial component of undergraduate and postgraduate education in medicine as well as other disciplines like nursing and pharmacy¹¹. Appropriate training is essential to ensure understanding of pharmacotherapy for older patients based on pharmacokinetics and

pharmacodynamics, as well as ways to minimize ADRs¹⁸. Geriatric pharmacotherapy need to be evolved as a comprehensive multidisciplinary approach with more involvement from pharmacists and nurses. Pharmacists in the work setting should be challenged to be more involved in drug related aspects in collaboration with clinicians. There is a possibility of involving pharmacists in geriatric clinics or geriatric care, who could contribute a lot in patient education, assisting clinicians in drug therapy selection and reviewing prescriptions for DRPs. Further, nurses should be more actively involved in geriatric clinics with regard to drug therapy issues. Guidelines or protocols could be developed institutionally, locally and regionally on geriatric drug use with emphasis on drug safety by a multidisciplinary approach.

An important aspect which has not gained much attention and participation among practitioners is the pharmacovigilance programmes; National ADR monitoring and reporting programmes. It should be considered that it is the responsibility of the individual practitioners to report to the regulatory bodies the adverse effects observed in their patients. This has more value in elderly population as the data on adverse effects among elderly are limited, as they are generally excluded in the pre-marketing clinical trials. Such reporting can add to the limited safety data available, identifying any unique drug responses in elderly, specific predisposing factors and methods to prevent the same. Drug safety studies in this age group need to be carried out more extensively at institutional, regional and national level.

Jimmy Jose

School of Pharmacy, University of Nizwa Birkat Al Mouz PB 33, PO 616, Nizwa Sultanate of Oman jimmy jose2001@yahoo.com

References

- Central Statistics Office. Government of India. Situation analysis of the elderly in India. June 2011. Available from: http://mospi.nic.in/mospi_new/upload/elderly_in_india.pdf, accessed on April 12, 2012.
- Rajan SI. The Centre for Enquiry into Health and Allied Themes (CEHAT), Population ageing and health in India. Available from: http://www.cehat.org/humanrights/rajan.pdf, accessed on April 12, 2012.
- Tangiisuran B, Wright J, Van der Cammen T, Rajkumar C. Adverse drug reactions in elderly: challenges in identification and improving preventative strategies. *Age Ageing* 2009; 38: 358-9.

- Zaveri HG, Mansuri SM, Patel VJ. Use of potentially inappropriate medicines in elderly: A prospective study in medicine out-patient department of a tertiary care teaching hospital. *Indian J Pharmacol* 2010; 42:95-8.
- Harugeri A, Joseph J, Parthasarathi G, Ramesh M, Guido S. Prescribing patterns and predictors of high-level polypharmacy in the elderly population: A prospective surveillance study from two teaching hospitals in India. Am J Geriatr Pharmacother 2010; 8: 271-80.
- Shah RB, Gajjar BM, Desai SV. Evaluation of the appropriateness of prescribing in geriatric patients using Beers criteria and Phadke's criteria and comparison thereof. *J Pharmacol Pharmacother* 2011; 2:248-52.
- Mandavi, D'Cruz S, Sachdev A, Tiwari P. Adverse drug reactions & their risk factors among Indian ambulatory elderly patients. *Indian J Med Res* 2012; 136: 404-10.
- Starner CI. Gray SL, Guay DRP, Hajjar ER, Handler SM. Hanlon JT. Geriatrics. In: Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM, editors. *Pharmacotherapy-A* pathophysiologic approach. 7th ed. USA: McGraw Hill Companies; 2008. p, 57-66.
- Kim J, Mak M. Geriatric drug use. In: Koda-Kimble MR, Young LY, Alldredge BK, Corelli RL, Guglielmo BJ, Kradjan WA, Williams BR, editors. *Applied therapeutics- The clinical* use of drugs, 9th ed. Philadelphia: Lippincott Williams & Wilkins; 2009. p. 99-1-99-20.
- Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency hospitalizations for adverse drug events in older Americans. N Engl J Med 2011; 365: 2002-12.
- Hamilton HJ, Gallagher PF, O'Mahony D. Inappropriate prescribing and adverse drug events in older people. BMC Geriatr 2009; 9:5.
- Singh P, Yadav RJ, Pandey A. Utilization of indigenous systems of medicine and homoeopathy in India. *Indian J Med Res* 2005; 122: 137-42.
- Fick DM, Cooper JW, Wade WE, Waller JL, MacLean JR, Beers MH. Updating the Beer's criteria for potentially inappropriate medication use in older adults Results of a US consensus panel of experts. *Arch Intern Med* 2003, *163*: 2716-24.
- Gallagher P, Ryan C, Byrne S, Kennedy J, O'Mahony D: STOPP (Screening Tool of Older Persons' Prescriptions) and START (Screening Tool to Alert Doctors to Right Treatment): Consensus Validation. *Int J Clin Pharmacol Ther* 2008; 46: 72-83.
- Chrischilles E, Rubenstein L, Van Gilder R. Risk factors for adverse drug events in older adults with mobility limitations in the community setting. *J Am Geriatric Soc* 2007; 55: 29-34.
- Buck ML, Kelsey JL. Drug use in special patient populations: Pediatric, pregnant, and geriatric. In: Shargel L, Mutnick AH, Souney PF, Swanson LN, editors. *Comprehensive pharmacy review* (South Asian edition), 7th ed. New Delhi: Wolters Kluwer (India); 2010. p. 754-74.
- 17. Gurwitz JH, Field TS, Harrold LR. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. *JAMA* 2003; *289*: 1107-16.
- Gray CL, Gardner C. Adverse drug events in the elderly: An ongoing problem. J Manag Care Pharm 2009; 15: 568-71.